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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,581	02/18/2004	Liam Seery	8912/2015	2809
29933	7590	12/20/2005		
PALMER & DODGE, LLP			EXAMINER	
KATHLEEN M. WILLIAMS			KOLKER, DANIEL E	
111 HUNTINGTON AVENUE				ART UNIT
BOSTON, MA 02199				PAPER NUMBER
			1649	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/781,581	SEERY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 18 February 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-12 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-12 are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1)  Notice of References Cited (PTO-892)  
 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5)  Notice of Informal Patent Application (PTO-152)  
 6)  Other: \_\_\_\_\_

**DETAILED ACTION*****Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 – 6, drawn to methods of identifying an agent that modulates the function of an apoptosis-associated protein, classified in class 435, subclass 7.1, for example.
  - II. Claims 7 – 10, drawn to methods of determining whether a chemical compound specifically binds to and inhibits an apoptosis-associated protein, classified in class 435, subclass 7.1, for example.
  - III. Claims 11 - 12, drawn to methods for identifying an agent that inhibits tumor cell proliferation, classified in class 435, subclass 7.1, for example.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each comprise different methods which require different steps and cannot be substituted one for the other. For example, Group I requires detecting the presence or absence of a signal generated from interactions of two proteins. This is not required for either Group II or Group III. Group II requires measuring second messenger responses, which is not required for either Group I or Group III. Group III requires determining whether tumor proliferation is inhibited, and this step is not required for either of Groups I and II. Furthermore, as consideration of each group requires search for each of the steps, consideration of more than one Group together would be burdensome for the examiner, as the searches are not coextensive.

***Requirement for Further Restriction Within All Groups***

3. All groups encompass screening methods wherein one of several proteins is to be analyzed. Each protein is a patentably distinct chemical entity that has unique biochemical and physical properties, and they cannot be substituted one for the other. Furthermore, search for methods of using any one protein would be uninformative as to the methods of using any other protein. Thus, in response to this requirement, applicant must elect for prosecution on the merits a single protein that is encoded by a gene selected from Table 1B. Applicant is advised

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that a reply to this requirement must include an identification of the elected protein, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. As each protein is patentably distinct and requires separate search and consideration, further restriction is proper. Applicant is advised that this additional requirement is not a species election.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and each require separate searches, restriction for examination purposes as indicated is proper.

***Requirement for Election of Species Within Group II***

5. If applicant elects group II for prosecution on the merits, applicant must also elect a single species for prosecution on the merits as set forth below.

This application contains claims directed to the following patentably distinct species of the claimed invention:

**SPECIFIC SECOND MESSENGER RESPONSES**

- a) chloride channel activation
- b) a change in intracellular calcium ion levels
- c) a release of inositol phosphate
- d) a release of arachidonic acid
- e) GTP-gamma-S binding
- f) activation of MAP kinase
- g) cAMP accumulation
- h) a change in intracellular potassium ion levels
- i) a change in intracellular sodium ion levels
- j) a change in reporter gene activity

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 7 is generic with respect to the second messenger.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker

December 6, 2005

  
SHARON TURNER, PH.D.  
PRIMARY EXAMINER

1213-07